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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,503	02/18/2004	Matthew F. Ogle	3126.03US02	2970

62274 7590 03/18/2008

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,503	OGLE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/20/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-37 and 47-52* is/are pending in the application.

4a) Of the above claim(s) *48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-37,47 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/04, 09/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group G in the reply filed on December 20 2008 is acknowledged.

2. Claims 48-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 20 2008. Claim 48 is withdrawn as it is drawn to the nonelected species of Figure 3. Claims 49-51 are withdrawn as they are drawn to the nonelected species of Figures 9A and 9B.

Information Disclosure Statement

3. Part of the information disclosure statement filed November 16 2008 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it appears that the following patent numbers were given in error: U.S. Patent No. 4,429,939 and U.S. Patent No. 6,458,502. The information disclosure statement has been placed in the application file, but the information which has been crossed out therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement,

including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 240, 242, 358. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 280, 282. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if

only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to because it appears that reference numerals 322 and 324 in Figure 11 should be labeled as reference numerals 332 and 334 (see lines 3-11 of page 41). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: The use of “(22,23)” in line 20 of page 21, “(19, 20)” in line 16 of page 22, and "(21)' in line 20 of page 22 is objected to as it is unclear what these numerals are representing.

Appropriate correction is required.

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification fails to disclose the SCF fiber having a surface area of at least about a factor of 1.5 greater than a corresponding circular fiber with an equivalent diameter.

Claim Objections

9. Claims 20-37, 47, and 52 are objected to because of the following informalities:

In claims 20, 25, 28, 31, 33, 34, 37, and 47, the use of the phrases "SCF fiber" or “SCF fibers” is unclear as “SCF” has not been defined in the claims. Similarly, the use of "tPA" in claim 23 is unclear and should be replaced with "tissue plasminogen activator". Claim 27 recites the limitation "the SCF fibers" in line 2. Claim 31 recites the limitation "the SCF fibers" in line 1. There is insufficient antecedent basis for this limitation in these claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 20, 25-31, 33-37, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Deniega et al (U.S. Patent No. 6,350,253). In Figure 6, Deniega et al show a medical device (52) with an SCF fiber (54). In lines 47-63 of column 9, Deniega et al disclose a quantity of bioactive agent associated with the SCF fiber. The SCF fiber is considered to have a surface area of at least about a factor of 1.5 greater than a corresponding circular fiber with an equivalent diameter. The device is configured for placement within a blood vessel without blocking flow through the vessel. The device comprises a catheter and the SCF fibers are associated with the inner surface of the catheter as seen in Figure 6. As to claim 28, Deniega et al disclose a tubular medical device (52) comprising a tubular substrate having an interior surface, an exterior surface, and at least one SCF fiber associated with at least a portion of one of the surfaces where the at least one SCF fiber is associated with a bioactive agent. The tubular medical device is a catheter or a microcatheter. As to claim 34, Deniega et al disclose a medical device (52) comprising a non-porous surface where at least a portion of the surface is covered with SCF fibers which are associated with a bioactive agent. The non-porous surface comprises a polymer (lines 1-6 of column 9) and is contoured to match a portion of a structure within a patient. As to claims 47, Deniega et al

disclose a method for delivering a bioactive agent where a patient's body fluids/tissues contact an SCF fiber associated with the bioactive agent (lines 47-63 of column 9).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 21, 22, 24, 32, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of DiCarlo et al (U.S. Patent No. 6,929,626). Deniega et al disclose the device and method substantially as claimed. Even though Deniega et al disclose a bioactive agent or medication associated with the SCF fiber(s), Deniega et al are silent as to the specifics of the bioactive agent being a thrombolytic agent such as heparin sulfate or a microbial agent. DiCarlo et al disclose a medical device (10) with SCF fibers (18, 22) where a bioactive agent is associated with the SCF fibers (lines 1-23 of column 13). DiCarlo et al disclose the bioactive agent comprising a thrombolytic agent, a microbial agent, or heparin sulfate (lines 24-44 in column 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Deniega et al a thrombolytic agent such as heparin sulfate or a microbial agent as taught by DiCarlo et al as both Deniega et al and DiCarlo et al disclose medical devices with SCF fibers and a bioactive agent associated with the SCF fibers and DiCarlo et al teach that it is well known to use a thrombolytic

agent such as heparin sulfate or a microbial agent for the bioactive agent which is being delivered into the patient's body.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of Samson et al (U.S. Patent No. 6,066,149). Deniega et al disclose the device and method substantially as claimed. Even though Deniega et al disclose a bioactive agent or medication associated with the SCF fiber(s), Deniega et al are silent as to the specifics of the bioactive agent comprising tPA. Samson et al disclose using a medical device or catheter to deliver bioactive agents such as tPA or urokinase (lines 19-27 of column 5) which are thrombolytic agents. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Deniega et al a thrombolytic agent such as tPA as taught by Samson et al as both Deniega et al and Samson et al disclose medical device for delivering a bioactive agent and Samson et al teach that it is well known to use a thrombolytic agent such as tPA for the bioactive agent which is being delivered into the patient's body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571) 272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767